REMARKS

The Examiner's comments from the Office Action mailed December 28, 2007 have been carefully considered. Claims 17, 19 and 39-62 are pending. Claims 47, 56 and 62 have been amended. Support for the amendments can be found in at least Figures 1-3 and the related description of those Figures in the present application. No new matter has been added. Reexamination and allowance of the pending claims is respectfully requested.

Claims 17, 19, and 39, 40, 46, 57, 58 and 61 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi (US 6,325,826). Applicants respectfully traverse this rejection.

The pending claims are directed to a system that includes a balloon catheter and a stent. The catheter includes a balloon that is positioned within a body of the stent and expands the stent body when inflated. The stent includes a plurality of movable members mounted to the stent body that are movable into a radially outward orientation upon expansion of the stent body by the balloon. Claim 17 recites that the stent body is expandable "from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body, in the unexpanded condition the plurality of moveable members being retained substantially within the circumferential plane of the stent wall and in the expanded condition a portion of the plurality of moveable members being extended radially outward from the stent wall to form a scaffold." Independent claim 57 recites a plurality of moveable members engaged to the stent wall that move from "an unexpanded position retained substantially within the circumferential plane to an expanded position extending generally radially outward from the stent wall when activated by expansion of the stent wall." Independent claim 61 recites "the single balloon extending within the stent body from at least a distal end to at least a proximal end of the stent wall, the stent wall and the moveable members being expandable by expansion of the single balloon." A primary aspect of each of independent claims 17, 57 and 61 is that the plurality of moveable members engaged to the stent wall automatically move into a radially outward extending position upon expansion of the tubular stent wall by inflation of the single balloon within the stent wall.

The rejection contends that Lam discloses a plurality of moveable members of a stent that meet the limitations of independent claims 17, 57 and 61 because Lam discloses a hybrid stent

that includes balloon expandable and self-expandable portions. However, Applicants submit that the disclosure of Lam actually teaches away from the limitations of claims 17, 57 and 61. Lam discloses at column 7, lines 37-67 an embodiment in which an ostial stent 44 (not shown in the Figures) can comprise a memory-retaining material such as NiTi. The memory-retaining material is heat activated such that at a cold temperature the stent would have an unexpanded and undeformed configuration, and at an increased temperature the stent would have an expanded and deformed configuration. During transport to a diseased area of a vessel, the cold temperature of the stent would be maintained, and upon arrival at the diseased area the stent would be subjected to an increased temperature that activates the stent to deform and expand. The deformed and expanded configuration would be retained at normal body temperature.

Lam goes on to discuss that the memory-retaining ostial stent 44 could be used with a balloon catheter, wherein the balloon catheter would contain a cold temperature fluid during delivery of the stent to the diseased area to maintain the stent in the unexpanded configuration, and the cold fluid would be removed and replaced with a high temperature compound that would cause the memory-retaining ostial stent 44 to deform and expand, thereby seating within and capping a diseased vessel.

Lam further discloses at column 7, lines 62-67:

> It is also contemplated that only a portion of the ostial stent 44 be comprised of a memory-retaining material. For this stent, balloon expansion can be utilized to expand or deform a portion of the stent that was not comprised of memory-retaining material.

The rejection refers to this type of stent as a hybrid stent that has a portion that is balloon expandable and another portion that is self-expandable. Applicants note that the only type of memory-retaining material disclosed by Lam is a heat activated material. Thus, the hybrid stent disclosed at column 7, lines 62-67 of Lam includes a portion that is expandable by inflation of a balloon, and another portion of the stent that is expandable by changing a temperature of a memory-retaining material to cause the memory-retaining material to deform and expand. In contrast to the requirements of claims 17, 57 and 61, Lam specifically requires that balloon expansion can be utilized to expand or deform a portion of the stent that was not comprised of the memory-retaining material. Thus, the memory-retaining material can be activated only by change in temperature and not by the mere expansion of the balloon expandable portion of the

stent. As noted above, claims 17, 57 and 61 recited that the moveable members move into a radially outward extending orientation relative to the stent wall upon expansion of the balloon expandable portions of the stent, in contrast to the heat activated memory-retaining portions taught by Lam. Thus, Applicants submit that Lam teaches away from the limitations of claims 17, 57 and 61.

Vardi fails to remedy the deficiencies of Lam as it relates to claims 17, 57 and 61. Vardi merely discloses a stent having a plurality of moveable members that extend from a stent wall to define a side opening of the stent wall. Specifically, Vardi discloses with reference to Figures 7-9, a main stent 40 with expandable portions 38 surrounding an opening 16, wherein the expandable portions are moved into a radially outward orientation by passing a balloon 25 along a branch guidewire 36 through the opening 16 and then inflating the balloon 25. The expandable portions 38 are not moveable into the radial outward orientation when the main body portion of the stent 40 alone is expanded. It is only by passing a balloon catheter through the opening 16 and expanding that balloon catheter that the expandable portions 38 are moved into the radial outward orientation.

Thus, Applicants submit that neither Lam, Vardi, nor a combination of these references disclose or render obvious every limitation of claims 17, 57 and 61, and the claims that depend from them. Withdrawal of the rejection is respectfully requested.

Claims 41-45, 47-56, 59, 60 and 62 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi (US 6,325,826), and further in view of Crocker (US 5,843,116). Applicants respectfully traverse this rejection.

As discussed above, Lam and Vardi, alone or in combination, fail to disclose or render obvious every limitation of claims 17 and 57. Crocker fails to remedy the deficiencies of Lam and Vardi as they relate to claims 17 and 57. Therefore, claims 41-45, 59 and 61 are allowable for at least the reason they are dependent upon an allowable base claim. Applicants do not otherwise concede the correctness of this rejection as it relates to claims 41-45, 59 and 60.

Claims 47 and 62 are directed to a catheter system that includes a balloon catheter and a stent. The balloon catheter includes a balloon arrangement (claim 47) or a single balloon (claim 62) that includes an elongate body and a bulge that protrudes radially outward from the body when the bulge is expanded. The bulge is positioned on the body at a location between proximal

and distal ends of the body and extends around less than an entire circumference of the body. The stent includes a substantially tubular stent wall and a plurality of moveable members that are extendable radially outward from the stent wall. The bulge is positioned within a circumferential plane defined by the stent wall prior to expansion of the bulge. After expansion of the bulge, a portion of the bulge is positioned within the circumferential plane and a portion of the bulge extends outside the circumferential plane through the side opening of the stent.

Lam discloses an ostial stent that is intended to be seated in a branch vessel at a vessel bifurcation with a flared portion 25 of the stent extending from a distal end of the stent for anchoring within a main vessel of the vessel bifurcation.

In contrast, Vardi discloses a stent 40 positioned within a main vessel of a vessel bifurcation, wherein the stent 40 includes a plurality of expandable members 38 that define an opening 16 in a side wall of the stent 40. The expandable members 38 expand radially outward relative to the side wall of the stent and into a branch vessel of the vessel bifurcation. As described above, Vardi discloses movement of the expandable members 38 by extending a balloon catheter along a guidewire that extends through the side opening into the branch vessel, and then expanding the separate balloon catheter.

Neither Lam nor Vardi discloses or suggests use of a balloon catheter having a bulge portion at a position between proximal and distal ends, wherein the bulge portion extends around only a portion of the circumference of the balloon. Lam and Vardi also fail to disclose or suggest the use of a bulge portion of a balloon to expand a plurality of moveable members of a stent that are positioned between proximal and distal ends of the stent. Still further, Lam and Vardi fail to disclose or suggest in any way a bulge portion of a balloon that is positioned within a circumferential plane of the stent prior to expansion of the bulge portion, and after expansion of the bulge portion of the bulge portion is positioned within the circumferential plane and a portion of the bulge portion extends through the side opening radially outside the circumferential plane," as required by claims 47 and 62.

Crocker fails to remedy the deficiencies of Lam and Vardi as they relate to claims 47 and 62. Crocker teaches a balloon catheter wherein the balloon includes a bulge region 30 that extends around an entire circumference of the balloon. The rejection points to column 1, lines 10-15 of Crocker for support that the bulge could be positioned at a predetermined

circumferential location on the balloon. However, the only examples described and illustrated by Crocker are limited to a bulge region that extends around an entire circumference as opposed to a bulge portion that extends around less than an entire circumference of the balloon as required by claims 47 and 62. Furthermore, the bulge region 30 disclosed by Crocker is not intended to extend through a side wall of the stent (i.e., from a position within a circumferential plane of the stent to a position outside the circumferential plane of the stent).

Crocker does disclose the use of a balloon catheter with a bulge portion around an entire circumference thereof for use in implanting a tubular graft within a body lumen. However, Crocker is completely silent as to the use of the example balloons disclosed therein for treating a vessel bifurcation wherein a portion of the implanted tubular graft extends from within one body lumen (i.e., a main vessel) in a radial outward direction relative to the graft for extension into a second body lumen (i.e., a branch vessel). Thus, the combination of Lam, Vardi and Crocker fail to disclose or render obvious a catheter system wherein the balloon of the catheter has a bulge portion that extends through a side opening of the stent to expand a plurality of moveable members of the stent into a radial outward orientation.

The rejection unofficially references US 5,935,135 (Bramfitt) for support of bulge regions of a balloon that extend around less than an entire circumference of the body portion of the balloon. Applicants submit that one of ordinary skill would not refer to Bramfitt in combination with the other cited references to develop the claimed catheter system. Bramfitt is directed to a balloon delivery system wherein the balloon includes cuff members at opposing proximal and distal ends of the stent to retain the stent axially during delivery of the stent to a treatment site in the vessel. There is no disclosure or suggestion whatsoever in Bramfitt of using the cuff members, whether continuous or around an entire circumference of the balloon or discontinuous cuff members, for expanding any portion of the stent. Furthermore, Bramfitt is completely silent as to the possibility of extending a cuff member through a side opening of the stent when the balloon is inflated.

Bramfitt further teaches away from the use of the cuff members to expand a portion of the stent at column 5, lines 1-13 wherein Bramfitt explains that "as the balloon is expanded, the cuffs 28 disappear into the wall of the balloon." Thus, one of ordinary skill referencing Bramfitt

would find no motivation to modify the teachings of Lam, Vardi and Crocker to include the bulge portion of the balloons required in claims 47 and 62.

In view of the above, Applicants submit that Lam, Vardi and Crocker, alone or in combination with each other or the Bramfitt reference fail to disclose or render obvious every limitation of claims 47 and 62 and the claims that depend from them. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance. If a phone conference would be helpful in resolving any further issues related to this matter, please contact Applicants' attorney listed below at 612-371-5387.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

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/Joshua N. Randall/
Joshua N. Randall
Reg. No. 50,719
JNR:ac:njo

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